K063847

FUJIFILM FUJINON

MAR 0 1 2007

510 (k) Summary

Date Prepared [21 CFR 807.92(a)(1)]

12/18/06

Submitter's Information [21 CFR 807.92(a)(1)]

This 510(k) is being submitted by Joseph Azary on behalf of Fujinon Inc.

Contact:

Joseph Azary

543 Long Hill Avenue

Shelton, CT 06484

Tel: (203) 944-9320

Fax: (203) 944-9317.

Sponsor / U.S. Distributor:

Fujinon Inc.

10 High Point Drive

Wayne, NJ 07470

FDA Establishment Registration# 2431293.

Manufacturer:

Fujinon Corporation

1-324 Uetake-Cho

Kita-Ku, Saitama-Shi

Saitama 331-9624, Japan

FDA Establishment Registration# 9610875

Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

Device Trade Name: Fujinon Ultrasonic Endoscope & Processor, EG-530UR, EG-530UT, SU-7000
Device Common, Usual, or Classification Names: Ultrasonic gastrointestinal endoscope, ultrasonic processor

Classification:

Product Code	Regulation Number	Description	Class
FDS	876.1500	Gastroscope	II
IYN	892.1550	Ultrasonic Pulsed Doppler Imaging System	II
IYO	892.1560	Ultrasonic Pulsed Echo Imaging System	II
ITX	892.1570	Diagnostic Ultrasonic Transducer	II

Predicate Device [21 CFR 807.92(a)(3)]

Ultrasonic Endoscopes

- Pentax EG-3630UR Ultrasound Video Gastroscope (K013640)
- Olympus GF-UE160-AL5 Endoscope (K051541)

The subject devices are substantially equivalent to the predicate devices. The indications for use are similar. There are only minor differences in field of view, viewing direction, diameter, and bending. The working length and total length are almost identical. Each endoscope uses different ultrasonic processors.

Ultrasound Processors

- Hitachi EUB-6000 (K994026 and K011252)

The subject device is substantially equivalent to the predicate device. The indications for use are similar. There are some minor differences in size and frequency.. The display modes, scanning mode, and display are almost identical.

Description of the Device [21 CFR 807.92(a)(4)]

The EG-530UR and EG-530UT are medical ultrasonic gastrointestinal endoscopes. They are intended for the observation and diagnosis of the upper digestive tract (including the esophagus, stomach, duodenum, and underlying areas) using an Ultrasonic endoscope, observation and diagnosis of submucosal and peripheral organs using ultrasonic images, and endoscopic treatment at medical facilities under the management of physicians.

These endoscopes are used in combination with a processor, light source, cart, ultrasonic processor (SU-7000), and video printer.

The endoscopes are used with a single use balloon. The endoscopes have a groove on the tip to hold the balloon in place.

The SU-7000 is an ultrasonic processor that is used with a medical ultrasonic endoscope (EG-530UR or EG-530UT). The processor connects to the ultrasonic endoscope, which emits ultrasound in a body cavity by driving an ultrasonic transducer of the endoscope. It also processes the reflection ultrasonic signal received by the transducer and coverts it to an ultrasonic image.

Intended Use [21 CFR 807.92(a)(5)]

Observation and diagnosis of the upper digestive tract (including the esophagus, stomach, duodenum, and underlying areas) using an Ultrasonic endoscope, observation and diagnosis of submucosal and peripheral organs using ultrasonic images, and endoscopic treatment

Technological Characteristics [21 CFR 807.92(a)(6)]

Fujinon, Inc. believes that the subject device is substantially equivalent to the predicate device. The subject device have similar indications for use.

Performance Data [21 CFR 807.92(b)(1)]

The subject device has been subjected to and passed electrical safety, thermal, and EMC testing requirements. The materials in the endoscope are biocompatible and are identical to the materials used in the predicate device.

Conclusion [21 CFR 807.92(b)(3)]

We believe the changes are minor and conclude that the subject devices are as safe and effective as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Fujinon, Inc.
% Mr. Joseph M. Azary
Azary Technologies, Inc.
543 Long Hill Avenue
SHELTON CT 06484

MAR 0 1 2007

Re: K063847
Trade/Device Name: Fujinon Ultrasonic Endoscope & Processor
(SU-7000 / EG-530UR / EG-530UT)
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Product Code: FDS
Regulation Number: 21 CFR §892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Product Code: IYN
Regulation Number: 21 CFR §892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Product Code: IYO
Regulation Number: 21 CFR §892.1570
Regulation Name: Diagnostic ultrasonic transducer
Product Code: ITX
Regulatory Class: II
Dated: December 18, 2006
Received: December 27, 2006

Dear Mr. Azary:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Fujinon Ultrasonic Endoscope & Processor SU-7000, as described in your premarket notification:

Transducer Model Number	
EG-530UT	EG-530UR

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

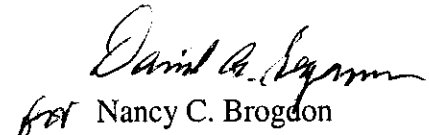
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Andrew Kang, M.D., at (240) 276-3666.

Sincerely yours,



for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

Indications for Use

510(k) Number (if known): K063847

Device Name: Fujinon Ultrasonic Endoscope & Processor (SU-7000 / EG-530UR / EG-530UT)

Indications For Use:

The EG-530UR and EG-530UT ultrasonic endoscopes are intended to be used with the SU-7000 ultrasound processor. The system is used for the observation and diagnosis of the upper digestive tract (including the esophagus, stomach, duodenum, and underlying areas), as well as observation and diagnosis of submucosal and peripheral organs using ultrasonic images, and endoscopic treatment.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063847

SU-7000

Appendix F

K063847

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal		N	N	N		N			See below	
Intraoperative (specify)		N	N	N		N			See below	
Intraoperative Neurological										
Pediatric		N	N	N		N			See below	
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal		N	N	N		N			See below	Non-Cardiac
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode includes B/M, B/PWD

Intraoperative: Gastro-intestinal tract & surrounding organs.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K063847

EG-530UT

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Abdominal		N	N	N		N			See below	
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Intraoperative: Gastro intestinal tract & surrounding abdominal organs.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K063847

Prescription Use (Per 21 CFR 801.109)

EG-530UR

Appendix F

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Diagnostic Ultrasound Indications for Use Form

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Abdominal		N	N	N		N			See below	
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